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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,969	03/21/2006	Hal C. Clark	CU60523	4574
20462 7590 12/19/2008 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
			EXAMINER	
			WEBB, GREGORY E	
		ART UNIT	PAPER NUMBER	
		1796		
		NOTIFICATION DATE	DELIVERY MODE	
		12/19/2008	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/572,969

**Applicant(s)**

CLARK ET AL.

**Examiner**

Gregory E. Webb

**Art Unit**

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment/Response to Arguments*

1. Applicant's arguments filed 11/20/08 have been fully considered but they are not persuasive.
2. The examiner agrees with those arguments concerning the newly added claims. And agrees that those claims are supported by the original presentation. As such a second final rejection is made below.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 34-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah et al (US 6491896) in view of Rajaiah et al (US 6509007).

Concerning the flavorant, and thickener, Rajaiah et al (US 6491896) teaches the following:

The denture cleansing compositions of the present invention can be supplemented by other known components of such formulations. Denture cleansing compositions of the invention can be supplemented by other usual components of such formulations, especially organic peroxyacid bleach precursors; lipophilic compounds including **flavorants**, physiological cooling agents, and perfumes; **surfactants**; chelating agents; enzymes; dyestuffs; sweeteners; tablet binders and fillers; foam depressants such as dimethylpolysiloxanes; foam stabilizers such as the fatty acid sugar esters; preservatives; lubricants such as talc, magnesium stearate, finely divided amorphous pyrogenic **silicas**, etc.; and additional therapeutic and cosmetic active agents. The free moisture content of the final composition is desirably less than about 1% and especially

less than about 0.5%.

Concerning the preferred thickener, Rajaiah, Jayanth teaches the following:

8. The denture cleanser composition of claim 7 wherein the dental abrasive is at a level from about 10% to about 70% by weight and is selected from the group consisting of **silica**, alumina, aluminosilicates, magnesium and zirconium silicates, calcium ortho-, pyro- meta- and polyphosphates, calcium and magnesium carbonates, insoluble metaphosphates and thermosetting polymerized resins.

Concerning the surfactant, denture adhesive, denture, and the preferred surfactant, Rajaiah, Jayanth teaches the following:

Another optional ingredient of the denture cleansing compositions of the invention is a **surfactant**. The **surfactant** can be selected from the many available that are compatible with the other ingredients of the **denture cleanser**, both in the dry state and in solution. Such materials are believed to improve the effectiveness of the other ingredients of the composition by aiding their penetration into the interdental surfaces. Also, these materials aid in the removal of food debris attached to the teeth. Between 0.1% and 5%, by weight of the dry composition of a dry powder or granular **anionic surface active agent**, such as sodium **lauryl sulfate**, sodium N-lauroylsarcosinate, sodium lauryl sulfoacetate or dioctyl sodium sulfosuccinate or ricinoleyl sodium

sulfosuccinate, may, for example, be included in the composition and in one embodiment the surfactant comprises between 0.5% and 4% of the composition.

7. Rajaiah et al (US 6491896) fails to teach the applicant's claimed applicator as well as the mineral oil. Rajaiah et al (US 6509007) also teaches composition suitable for oral care and specifically teaches kits for oral care which included an applicator. As both reference are by the same inventor, produced by the same company and specifically directed to oral care compositions, the examiner finds a clear nexus between these two references.

Concerning the preferred surfactant, Rajaiah, Jayanth(US 6509007) teaches the following:

The oral care compositions of the present invention may also comprise surfactants, commonly referred to as sudsing agents. Suitable surfactants are those that are reasonably stable and foam throughout a wide pH range. The surfactants are present at a level of from about 0.001% to about 12%, in one embodiment from about 0.01% to about 8%, and in another embodiment from about 0.1% to about 6%, by weight of the oral care carrier component of the oral care composition. The surfactant may be anionic, nonionic, amphoteric, zwitterionic, cationic, or mixtures thereof. Anionic surfactants useful herein include the water-soluble salts of alkyl sulfates having from 8 to 20 carbon atoms in the alkyl radical (e.g., sodium alkyl sulfate) and the water-soluble

salts of sulfonated monoglycerides of fatty acids having from 8 to 20 carbon atoms.

Sodium **lauryl sulfate** and sodium coconut monoglyceride sulfonates are examples of **anionic surfactants** of this type. Other suitable **anionic surfactants** are sarcosinates, such as sodium lauryl sarcosinate, taurates, sodium lauryl sulfoacetate, sodium lauroyl isethionate, sodium laureth carboxylate, and sodium dodecyl benzenesulfonate.

Mixtures of anionic surfactants can also be employed. Many suitable anionic surfactants are disclosed in U.S. Pat. No. 3,959,458, to Agricola, et al., incorporated herein in its entirety by reference. Nonionic surfactants which can be used in the compositions of the present invention can be broadly defined as compounds produced by the condensation of alkylene oxide groups (hydrophilic in nature) with an organic hydrophobic compound which may be aliphatic or alkyl-aromatic in nature. Examples of suitable nonionic surfactants include poloxamers (sold under trade name Pluronic), polyoxyethylene sorbitan esters (sold under trade name Tweens), fatty alcohol ethoxylates, polyethylene oxide condensates of alkyl phenols, products derived from the condensation of ethylene oxide with the reaction product of propylene oxide and ethylene diamine, ethylene oxide condensates of aliphatic alcohols, long chain tertiary amine oxides, long chain tertiary phosphine oxides, long chain dialkyl sulfoxides, and mixtures of such materials. The amphoteric surfactants useful in the present invention can be broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be a straight chain or branched and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic water-solubilizing group, e.g., carboxylate, sulfonate, sulfate, phosphate, or phosphonate. Other suitable

amphoteric surfactants are betaines, specifically cocamidopropyl betaine. Mixtures of amphoteric surfactants can also be employed. Many of these suitable nonionic and amphoteric surfactants are disclosed in U.S. Pat. No. 4,051,234, Gieske, et al., incorporated herein by reference in its entirety.

Concerning the sulfate, and flavorant, Rajaiah, Jayanth(US 6509007) teaches the following:

Oral care carrier component #3 is prepared by conventional means. sodium fluoride, saccharin and water to a mixing vessel. Disperse the **thickeners**, carboxymethylcellulose, in the **glycerin** and sorbitol before adding to the mixture. Add the **propylene glycol, flavorant**, titanium dioxide and sodium alkyl **sulfate**. Next add the sodium carbonate, **silica** and sodium bicarbonate. Continue mixing until homogenous. Mill and/or deaerate the final product if desired for aesthetic preference.

Concerning the silicas, preferred oil-based solvent, mineral oil, thickener, and preferred thickener, Rajaiah, Jayanth(US 6509007) teaches the following:

The oral care kits and compositions may further comprise a viscosity modifier that inhibits settling and separation of components or controls settling in a manner that facilitates re-dispersion and may control flow properties. A viscosity modifier is particularly useful to keep oral care actives that are in particulate form suspended within



the polybutene components of the present invention. Suitable viscosity modifiers herein include **mineral oil**, organo modified clays, petrolatum, **silicas**, and mixtures thereof. In one embodiment the viscosity modifier is **silica**. Where incorporated, the viscosity modifier is present in the polybutene component of the present invention at a level of from about 0.1% to about 30%, in one embodiment from about 0.5% to about 10%, and in another embodiment from about 1% to about 3% of the composition.

Concerning the applicator, Rajaiah, Jayanth teaches the following:

In practicing the oral care kits and compositions of the present invention, the user applies the oral care compositions disclosed herein directly to the tooth surfaces. Where an **applicator** is included in the kit, the composition can be applied using the brush, pen **applicator**, doe's foot **applicator**, tray, stint or any other supplied application device known in the art. Where an **applicator** is not provided with the oral care kit or compositions of the present invention, the composition may also be applied by finger, cotton swab, or **dental** stick or the like. Where an oral care carrier is incorporated within the present invention, the composition is in the form of a dentifrice, toothpaste, mouth rinse, mouth spray, topical oral gel or whitening gel, the compositions are applied through traditional means. For example, toothpaste compositions are applied through brushing with a toothbrush; mouth rinse is applied by swishing the composition in the oral cavity and expectorating.

8. As both Rajaiah references teach oral care compositions containing many of the same ingredients, the inclusion of an applicator and mineral oil is an obvious addition to an oral care composition. Rajaiah provides motivation for the inclusion of these two components. As for the applicator it clearly states that an applicator would provide the user with a means of apply the composition without having to use one's finger. Concerning the mineral oil, Rajaiah teaches this compound to be beneficial in modifying the viscosity of the composition.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory E. Webb whose telephone number is 571-272-1325. The examiner can normally be reached on 9:00-17:30 (m-f).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory E. Webb/  
Primary Examiner, Art Unit 1796

Gregory E. Webb  
Primary Examiner  
Art Unit 1796

gew  
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